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EXAMINER	
BLATT, ERIC D	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
03/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/613,502	BEANE ET AL.	
	Examiner	Art Unit	
	Eric Blatt	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-17 and 20-28* is/are pending in the application.

4a) Of the above claim(s) *15-17 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 14, and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 recites that a distal end of the suturing assembly has an outer diameter less than an outer diameter of a proximate end of the suturing assembly. It is unclear what end is proximate, taken to mean nearby, the distal end of the suturing assembly. Presumably, a middle portion, rather than an end, is proximate the distal end. Examiner believes Applicant may have intended to refer to the *proximal* end of the suturing assembly.

Claim 28 recites, “a distal end of the needle plunger attaches to a proximal end of the needle by means of a thin rod and a cylindrical region of the suturing assembly that is between the proximal end of the suturing assembly and the distal end has an aperture for the needle to exit from the suturing assembly." These recitations are difficult to understand as it is unclear how the conjunctions tie the limitations together. Presently, Examiner understands this language to mean a distal end of the plunger attaches to a proximal end of the needle by means of a thin rod. Additionally, there is a cylindrical region on the suturing assembly between its distal and proximal ends

wherein said cylindrical region has an aperture for the needle to exit from the suturing assembly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130).

Regarding claims 1, 2, and 6-8 Poloyko discloses a surgical suture placement device (Figures 2 and 3) comprising a handle assembly comprising a plunger 62, a suturing assembly having a needle 52, and a hollow inner tube 36 running between the handle assembly and the suturing assembly wherein the hollow inner tube 36, handle assembly, and suturing assembly are non-rotatably connected to one another. Polyoko fails to disclose an elongated hollow outer tube provided over the hollow inner tube 36 wherein the outer tube is rotatable relative to the handle assembly, inner tube 36, and suturing assembly. Poncet discloses a related minimally invasive device (Figure 2) wherein a distal tool 11 is non-rotatably coupled to an inner member 19, and an outer member 17 is provided over the inner member 19 wherein the outer member 17 is rotatable relative to the tool 11 and inner member 19. This construction allows the tool to be rotated about its axis from the handle of the device without rotating the tissue-

contacting surface of the shaft, thereby minimizing trauma to the surrounding tissue when changing the orientation of the tool. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing an elongated hollow outer tube over the inner tube 36 wherein the outer tube is rotatable relative to the handle assembly, inner tube 36, and distal tool as taught by Poncet in order to minimize trauma to the surrounding tissue while changing the orientation of the tool. So modified, the hollow outer tube is connected at a proximal end to the handle assembly, is rotatably secured at a distal end to the suturing assembly, and is the hollow inner tube is located within the hollow outer tube. Rotating the handle assembly while holding the outer tube stationary concurrently rotates the hollow inner tube 36 and the suturing assembly as a unit.

As shown in Figure 2, the suturing assembly has a distal end that at its tip is arc shaped in the cross-section shown in the drawing. Since the distal end of the device tapers somewhat, the outer diameter at this point is less than an outer diameter of a proximate end of the suturing assembly. There is an exterior of the device (along the shaft of the device) between the handle assembly and the distal end of the suturing assembly that has a substantially consistent diameter.

The suturing assembly comprises a holding member (track containing needle therein), also considered to be a needle guide having suture aperture 48, that removably holds the needle 52, and a needle cover 38. There is a thin flexible rod 64 arranged within the hollow inner tube 36 wherein the rod is connected at a proximal end to the handle assembly and has a distal end configured for connection to a needle

located within the suturing assembly. The plunger 62 attaches to the needle by means of the thin rod 64.

Regarding claims 3-5, Poloyko does not teach that the needle is hollow and has an open, sharp tipped distal end with rounded edges such that a suture may extend from an aperture on a proximal surface of the needle to an opening at the distal end of the needle. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide such a needle since such needles were notoriously old and well known to be used for suturing.

Regarding claim 7, all materials have some degree of flexibility. Alternatively, it would have been obvious to increase the flexibility of the shaft of the device in order to allow the device to access and suture more remote anatomies.

Regarding claim 9, Poloyko does not teach that there is a spring that biases the needle plunger into an extended position and the needle into a retracted position. It was well known to provide a spring on such plunger actuating mechanisms in order to bias the plunger into an extended position and the device into an non-actuated position. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing a spring that biases the needle plunger into an extended position and the needle into a retracted position in order to prevent the needle from projecting from the distal end without the surgeon intending for the needle to do so.

Regarding claims 10 and 11, Poncet teaches that the functional distal tool may be angled away from the longitudinal axis of the hollow outer tube. (Figure 1) It would

have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by having the suture assembly be angled away from the longitudinal axis of the outer tube in order to allow the suture assembly to access a wider variety of anatomies. It would have been obvious to have said angle be a 45 degree angle since the court has held that it is within the knowledge of a person skilled in the art to determine optimal range for the function of a device.

Regarding claim 26, the device of Poloyko is substantially rigid. Poncet teaches that such devices may be bent in order to allow the tools to reach more remote anatomies. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a bend along the shaft of the modified Poloyko device in order to achieve these benefits. So modified, the hollow outer tube would have a bent portion.

With regard to claim 27, the handle assembly includes a sleeve 35, 37 that is rigidly attached to the hollow inner tube of the unmodified device of Poloyko. Upon modifying the device as discussed above, an outer tube is placed around the inner tube to allow the inner and outer tubes to rotate relative to one another, thereby allowing the suturing assembly to be rotated without frictionally engaging tissue along the shaft of the device. It would have been obvious to one of ordinary skill in the art to instead attach the sleeve 35, 37 to the outer tube in order to provide a gripping point along the outer tube for a user to effect the desired relative rotation. Whether the sleeve 35, 37 is attached to the inner tube or outer tube is a matter of design choice since a user will be able to rotate the tubes relative to one another equally well in either configuration.

Interpreting the sleeve 35, 37 as part of the handle assembly, the portion of the device between the handle assembly and the suturing device consists of the hollow inner tube, the hollow outer tube and the rod.

Regarding claim 28, the aperture through which the needle exits the suturing assembly appears to lie on a substantially cylindrical portion of the suturing assembly. Although the drawings only show cross-sections of this portion of the device, the perimeter of the device is presumably rounded such that the device is cylindrical along an axis that roughly overlaps with the bore 48. Alternatively, it would have been obvious to make the perimeter of the device round since this is a standard feature on many instruments and making this modification would merely require a change in the shape of the device and would not materially impact its function. As seen in Figure 2, the aperture is between the proximal and distal ends of the suturing assembly.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130) and further in view of Andreas et al. (US 5,797,929).

Poloyko and Poncet teach all elements of claim 12 as previously discussed except for the hollow outer tube having a sleeve ridigly attached thereto wherein the sleeve has a diameter greater than the diameter of the hollow outer tube and the handle assembly is rotatable within the sleeve. Andreas teaches a related suturing system wherein a hollow outer tube 104 is rotatable relative to a handle assembly (includes element 140 and the proximal portion of shaft 106) and a hollow inner tube 106.

Andreas teaches providing a sleeve 130 at the proximal end of the hollow outer tube 104 having a diameter greater than that of the hollow outer tube. The handle assembly rotates within the sleeve 130. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus taught by Poloyko and Poncet by providing the outer tube with a sleeve as taught by Andreas in order to provide a user with a larger-diameter that may be gripped to more easily cause relative rotation between the inner and outer tubes. So modified, at least a portion of the the handle assembly would rotate within the sleeve.

Claims 14 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130) as applied to claim 1 above and further in view of Djurovic (US 6,315,784).

Regarding claims 14 and 25, Poloyko and Poncet teach all elements of claim 14 as previously discussed except for a suture holder attached to the needle guide wherein the needle guide is secured between the needle cover and the suture holder. The suture material of Poloyko is fed from a supply outside the body through the flexible actuating rod and to the suturing assembly. Djurovic teaches that a suture holding spool containing a supply of suture material may be attached at the distal end of a suturing device. (Figure 1) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing a suture holding spool within the suture assembly since Djurovic teaches that this was a known alternative for feeding suturing material to the needle. Since the needle cover 38 is the

outer housing of the suture assembly and the needle guide is the track containing the needle therein, by positioning the suture holder within the suture assembly as taught by Djurovic, the needle guide would be secured between the suture holder and at least some portion of the needle cover.

So modified, a spool is positioned within element 38, and a suture thread is fed from the spool to the needle 52 located within the curved needle guide. For this configuration to be possible, the suture must pass through a suture hole in the needle cover 38 and into the needle guide to reach the needle 52. As can be seen in Figure 2 of Poloyko, regardless of where the suture hole is located within element 38, it will be adjacent a concave portion of the curved needle guide.

Response to Arguments

Applicant's arguments filed 12-22-2009 have been fully considered but they are not persuasive. Applicant argues that Poloyko fails to disclose a narrowed tip on the suturing assembly that is arc shaped along an axial cross-section thereof. Examiner points to Figure 2 which clearly shows an arc shape at the distal end of the suturing assembly. Measured in a plane that is perpendicular to the longitudinal axis of the shaft of the device, the perimeter of the suturing assembly tapers toward its distal end. Applicant has additionally submitted that the exterior of the device of Poloyko changes along its length, and that it therefore fails to meet the recitation that between the handle assembly and the distal end of the suturing assembly, an exterior of the device has a substantially consistent diameter. First, Examiner notes that this language may be

broadly interpreted to require only that there exists an exterior of the device between the handle assembly and the distal end of the suturing assembly wherein said exterior has a substantially consistent diameter. The language does not require that the exterior runs the entire length between the handle assembly and the distal end of the suturing assembly. Poloyko clearly shows at least an exterior (the portion along the shaft) that has a substantially consistent diameter. Further, Examiner notes that the device has been modified such that an outer tube is added over the inner tube shown in Poloyko. One skilled in the art would have recognized that by changing the size of the outer tube or the suturing assembly, and a substantially consistent diameter could be easily be produced along the shaft and suturing assembly. Such a modification would have been advantageous to reduce friction with surrounding tissue as the device is inserted to a surgical site.

With regard to claims 27 and 28, sleeve 37 may be interpreted to comprise a portion of the handle assembly. Upon this interpretation, the modified device between the handle assembly and the suturing assembly consists of the hollow inner tube, the hollow outer tube and the rod. The suturing assembly appears to be substantially cylindrical at the location of the aperture 48 of Poloyko. Along the longitudinal axis of the shaft, the aperture 48 is located proximally of the distal end of the suturing assembly.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

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/Eric Blatt/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734